

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Allen David ROSES

Serial No.: To be assigned

Filed: Concurrently herewith

For: *Iterative Analysis of Non-Responding
Populations in the Design of
Pharmacogenetic Studies*

Mail Stop PATENT APPLICATION

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants request that the references identified on Form PTO-1449 appended hereto be considered by the Examiner and officially made of record in accordance with the provisions of 37 CFR 1.97

- ☐ Copies of the references are enclosed
☒ Copies of the references were submitted in parent application Serial No. 09/826,629 (37 CFR 1.98(d))
☐ A copy of the International Search Report which issued on International Application No. _____ is submitted herewith. All of the publications cited in the International Search Report are listed on the attached form PTO-1449 and Applicants understand that copies have been supplied to the U.S. Patent Office by the International Bureau.
- A. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing date of the above application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 CFR 1.97(b).
- OR
- ☐ The Information Disclosure Statement submitted herewith is being filed before the mailing of a first office action after the filing of a Request For Continued Examination under 37 C.F.R. 1.114 (37 C.F.R. 1.97(b)(4)).
- B. ☐ The Information Disclosure Statement transmitted herewith is being filed **after** three months of the filing date of the above application or the date of entry into the national stage as set forth in § 1.491 of an international application or after the mailing date of the first Office Action on the merits, whichever event occurred last, but **before** the mailing date of either:
- (1) a final action under § 1.113 or
- (2) a notice of allowance under § 1.311,
- whichever occurs first.
- ☐ Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ Applicant elects the option to pay the fee set forth in 37 CFR 1.17(p) for submission of an Information Disclosure Statement under § 1.97(c) (\$240.00).
- C. ☐ The Information Disclosure Statement transmitted herewith is being filed **after** a final action under § 1.113, or a notice of allowance under § 1.311, whichever occurs first, but before the payment of the

issue fee. Also enclosed is a copy of the International Search Report which Issued on International Publication No.

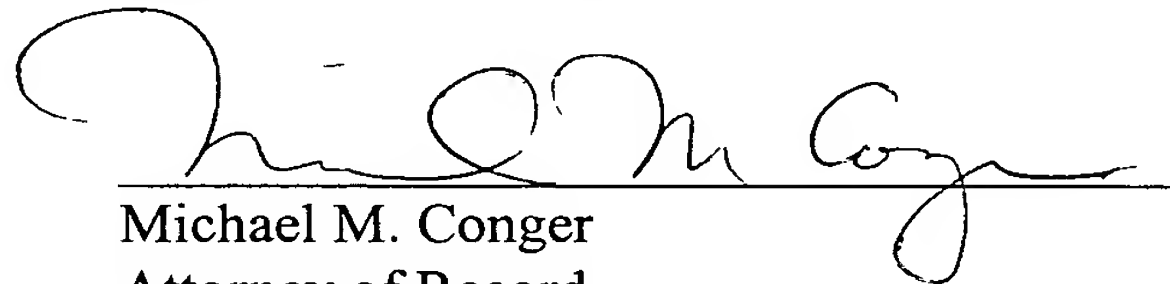
In accordance with the requirements of 37 CFR 1.97(d):

- ☐ Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ Applicant hereby petitions for the consideration of the accompanying Information Disclosure Statement. 37 CFR 1.97(d)(ii).
- ☐ The petition fee set forth in § 1.17(i)(1) (\$130.00) is submitted herewith.

☒ Please charge any required fees to Deposit Account No.07-1392.

☐ A duplicate copy of this paper is attached.

Respectfully Submitted,



Michael M. Conger
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Date: September 10, 2003
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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT				ATTORNEY DOCKET NO. PU3948US3		SERIAL NO. To be assigned	
				APPLICANT Allen David ROSES			
				FILING DATE Concurrently herewith		GROUP	
U.S. PATENT DOCUMENTS							
Examiner Initials		Patent Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate
	1.	5,360,800	11/01/1994	Coates et al.			
Continue on page _____							
FOREIGN PATENT DOCUMENTS							
		Document Number	Publication Date	Country	Class	Subclass	Translation Yes No
Continue on page _____							
OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)							
	2.	Bardhan et al., "A double-blind, randomized, placebo-controlled dose-ranging study to evaluate the efficacy of alosetron in the treatment of irritable bowel syndrome", <i>Aliment Pharmacol Ther</i> 14:23-34 (2000).					
	3.	Camilleri et al., "Improvement in pain and bowel function in female irritable bowel patients with alosetron, a 5-HT ₃ receptor antagonist", <i>Aliment Pharmacol Ther</i> 13:1149-1159 (1999).					
	4.	Collier et al., "A novel functional polymorphism within the promoter of the serotonin transporter gene: possible role in susceptibility to affective disorders", <i>Molecular Psychiatry</i> 1:453-460 (1996).					
	5.	Cotton et al., "Reactivity of cytosine and thymine in single-base-pair mismatches with hydroxylamine and osmium tetroxide and its application to the study of mutations", <i>Proc Natl Acad Sci USA</i> 85:12 4397-4401 (June 1988).					
	6.	Farthing, "Irritable bowel syndrome: new pharmaceutical approaches to treatment", <i>Baillière's Clinical Gastroenterology</i> 13:3 461-471 (1999).					
	7.	Furlong et al., "Analysis and Meta-Analysis of Two Serotonin Transporter Gene Polymorphisms in Bipolar and Unipolar Affective Disorders", <i>American Journal of Medical Genetics (Neuropsychiatric Genetics)</i> 81:58-63 (1998).					
	8.	Galernter et al., "Linkage mapping of serotonin transporter protein gene SLC6A4 on chromosome 17", <i>Hum Genet</i> 95:677-680 (1995).					
	9.	Haris et al., "Mutation Detection by Fluorescent Chemical Cleavage: Application to Hemophilia B", <i>PCR Methods and Applications</i> 3:268-271 (1994) by Cold Spring Harbor Laboratory Press.					
	10.	Heils et al., "Functional promoter and polyadenylation site mapping of the human serotonin (5-HT) transporter gene", <i>J Neural Transm [Gen Sect]</i> 102:247-254 (1995).					
	11.	Heils et al., "Allelic Variation of Human Serotonin Transporter Gene Expression", <i>Journal of Neurochemistry</i> 66:2621-2624 (1996).					
Continue on page <u>2</u>							
EXAMINER					DATE CONSIDERED		
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.							

APPLICANT Allen David ROSES	
FILING DATE Concurrently herewith	GROUP

U.S. PATENT DOCUMENTS

Examiner Initials		Patent Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate

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FOREIGN PATENT DOCUMENTS

		Document Number	Publication Date	Country	Class	Subclass	Translation Yes No

Continue on page ____

OTHER DOCUMENTS (Including Author, Title, Journal, Date, Page Number, Etc.)

	12.	Jones et al., "Alosetron relieves pain and improves bowel function compared with mebeverine in female nonconstipated irritable bowel syndrome patients", <i>Aliment Pharmacol Ther</i> 13:1419-1427 (1999).
	13.	Lesch et al., "Isolation of a cDNA encoding the human brain serotonin transporter", <i>J Neural Transm [GenSect]</i> 91:67-72 (1993).
	14.	Lesch et al., "Association of Anxiety-Related Traits with a Polymorphism in the Serotonin Transporter Gene Regulatory Region", <i>Science</i> 274:1527-1531 (November 1996).
	15.	Mangel et al., "Review article: the safety and efficacy of alosetron, a 5-HT ₃ receptor antagonist, in female irritable bowel syndrome patients", <i>Aliment Pharmacol Ther</i> 13 (Suppl. 2):77-82 (1999).
	16.	Manning et al., "Towards positive diagnosis of the irritable bowel", <i>British Medical Journal</i> 2:653-654 (September 1978).
	17.	Menza et al., "Depression and Anxiety in Parkinson's Disease: Possible Effect of Genetic Variation in the Serotonin Transporter", <i>J. Geriatr Psychiatry Neurol</i> 12:49-52 (1999).
	18.	Ramamoorthy et al., "Antidepressant- and cocaine-sensitive human serotonin transporter: Molecular cloning, expression, and chromosomal localization", <i>Proc. Natl. Acad. Sci. USA</i> 90:2542-2546 (March 1993).
	19.	Rosenthal et al., "Role of serotonin transporter promoter repeat length polymorphism (5-HTTLPR) in seasonality and seasonal affective disorder", <i>Molecular Psychiatry</i> 3:175-177 (1998).
	20.	Saslow et al., "Medium term effects of a new 5HT ₃ antagonist, alosetron, in patients with carcinoid diarrhoea", <i>Gut</i> 42:628-634 (1998).
	21.	Thompson et al., "Irritable Bowel Syndrome: Guidelines for the Diagnosis", <i>Gastroenterology International</i> 2:2 92-95 (1989).
	22.	Thompson et al., "Functional bowel disorders and functional abdominal pain", <i>Gut</i> 45 Suppl II:II43-II47 (1999).
	23.	Elston et al., <i>Statistics in Medicine</i> 18:741-751 (1999).
	24.	Kleyn et al., <i>Science</i> 281:1820-1821 (1998).
	25.	The Nature Biotechnology Roundtable ("Pharmacogenomics: Revolution or Reaction?" BIO 98' International Meeting and Exposition on June 16, 1998, New York, New York

Continue on page ____

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